

PSJ3

Exhibit 444

Appointment

**From:** Ducca, Anita [aducca@hdmanet.org]  
**Sent:** 7/18/2010 3:17:33 PM  
**To:** Ducca, Anita [aducca@hdmanet.org]; Bradley T. Pine (bpine@smithdrug.com); Bruce Russell (bruce.russell@mckesson.com); Debbie Walker (dwalker@amerisourcebergen.com); Lake, Debbie; Edward Steres (edsteres@bdipharma.com); Hal Harrison (hharrison@mutualdrug.com); Heather Zenk (hzenk@amerisourcebergen.com); J. Christopher Smith (csmith@hdsmith.com); Jake Stenner (bradley.stenner@mckesson.com); James K. McWilliams (james.mcwilliams@absg.com); Jason Gerstenberger (jgerstenberger@pssd.com); Jeffery W. Denton (jdenton@amerisourcebergen.com); Joe Lumpkin (jlumpkin@pssd.com); Howells, John; Ribler, Karen; Freitas, Kristen; Marc Falkin (marc.falkin@andanet.com); Beckloff, Michael; Michael Kody (mkody@amerisourcebergen.com); Warren, Neil; Fri, Perry; Peyton Howell (peyton.howell@absg.com); Robert E. Kashmer (rkashmer@hdsmith.com); Giacalone, Robert; Rolando DeCardenas (rolando.decardenas@usoncology.com); Ron Bone (ron.bone@mckesson.com); Decker, Scott; Melville, Scott; Shay Reid (sreid@amerisourcebergen.com); Stephen B. Mays (smays@amerisourcebergen.com); Reardon, Steve; Steve Tadevich (steve.tadevich@mckesson.com); Tad Strong (tstrong@pssd.com); Tish E. Pahl (tpahl@ofwlaw.com); Brookover, Wayne; Fri, Perry; Melville, Scott  
**Subject:** Reminder: Conference Call on FDA REMS Public Meetings Tomorrow, 7/15 at 3:00 pm ET  
**Attachments:** 07-15-2010 REMS TF agenda.doc; Potential talking points for FDA REMS Public Meetings 07-14-10 v.2.doc; Summary of FDA REMS Materials 07-07-10.pdf  
**Location:** Dial-In: 1-888-206-2266 Guest i.d. #2533738 -- HDMA Staff: Fairfax Conf Rm.  
**Start:** 7/15/2010 7:00:00 PM  
**End:** 7/15/2010 8:00:00 PM  
**Show Time As:** Tentative

*For HDMA distributor members only. Please do not circulate outside of your company's offices.*

Dear REMS TF Members:

This is to remind you of our *FDA REMS Meetings* conference call tomorrow **July 15 at 3:00 pm Eastern** and to provide a slightly modified version of the potential talking points for testimony. (For those involved in the Center's REMS Research, there is a separate *REMS Project Wrap-Up* conference call with Campbell Alliance earlier in the day. For those in the Regulatory Affairs Committee (RAC), there is also a separate RAC call that day.)

➤ **Dial-in number:** 1-888-206-2266

➤ **Guest #2533738**

➤ **HDMA Staff:** Fairfax Conference Room

I wanted to clarify that part of this call will cover whether HDMA should testify at all. Also, the attached potential talking points are meant to generate discussion and are not final HDMA recommendations. If we decide to testify, we'll discuss whether further refinements or alternative points are warranted.

Additionally,

1. Whether the advisory committee representatives meeting on the Opioids REMS (7/22 & 23) will expect wholesale distributors to perform any functions is unknown. However, FDA has not proposed a role for wholesale distributors in their draft. See the attached summary and this link:

<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm214816.htm>

2. FDA's questions related to distribution for the 7/27 & 28 REMS meeting are in the Federal Register under *C. Issues Regarding Elements to Assure Safe Use*, # 4.c and # 5.a&b

<http://edocket.access.gpo.gov/2010/pdf/2010-14547.pdf>

- 4. How have REMS with elements to assure safe use affected the health care delivery system?

c. How should REMS with elements to assure safe use be made compatible with established distribution systems so as to minimize the burden on the health care delivery system?

5. Some REMS are implemented by distribution of drugs through a central pharmacy system, and some are implemented through a retail pharmacy system.

a. What are the advantages and disadvantages of the various models of drug distribution under a REMS?

b. Should sponsors be permitted to choose the drug distribution system they prefer to manage the risks, or should a common distribution system be employed for REMS?

If you have any questions, please contact me at 703-787-0000.

<<07-15-2010 REMS TF agenda.doc>> <<Potential talking points for FDA REMS Public Meetings 07-14-10 v.2.doc>>



07-15-2010 REMS  
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Potential talking  
points for FDA R...



Summary of FDA  
REMS Materials ...

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